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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

05/15/2009

Brian R Morrill Biomeasure Incorporated 27 Maple Street Milford, MA 01757-3650 EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/15/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,398	01/21/2005	Zheng Xin Dong	113P/PCT3/US	5939

TITLE OF INVENTION: GHRELIN ANALOGS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/17/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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Brian R Morril Biomeasure Inco 27 Maple Street	orporated	/2009	I S ac tr	hereby certify that that the ates Postal Service valuessed to the Mai	iis Fee(vith sui l Stop	e of Mailing or Transı s) Transmittal is being fficient postage for firs ISSUE FEE address (1) 273-2885, on the da	deposited with the United t class mail in an envelope above, or being facsimile
Milford, MA 017	/5/-3650						(Depositor's name)
			-				(Signature)
			L				(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	OR .	ATTC	RNEY DOCKET NO.	CONFIRMATION NO.
10/522,398 TITLE OF INVENTION	01/21/2005 : GHRELIN ANALOGS		Zheng Xin Dong			113P/PCT3/US	5939
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EXAM	INER	ART UNIT	CLASS-SUBCLASS	7			
GUPTA,	ANISH	1654	514-012000	_			
 Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Custome Number is required. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED OF COMMENTED OF			(1) the names of up or agents OR, alternated (2) the name of a single registered attorney of a registered patent a listed, no name will THE PATENT (print or				
recordation as set fortl (A) NAME OF ASSIC	h in 37 CFR 3.11. Comp GNEE	oletion of this form is NO	T a substitute for filing a	in assignment. IY and STATE OR (COUNT	TRY)	up entity Government
4a. The following fee(s) are submitted: ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) A check is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form). 				
NOTE: The Issue Fee and	s SMALL ENTITY statu	us. See 37 CFR 1.27.	b. Applicant is no l				FR 1.27(g)(2). e assignee or other party in
interest as shown by the r	records of the United Sta	tes Patent and Trademark	Office.			-	
Authorized Signature			Date				
Typed or printed name			Registration No ation is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process)				
This collection of inform an application. Confident submitting the completed this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	tiality is governed by 35 I application form to the ons for reducing this but irginia 22313-1450. DC	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th O NOT SEND FEES OR (on is required to obtain of 1.14. This collection is depending upon the ine Chief Information Off COMPLETED FORMS	r retain a benefit by estimated to take 12 lividual case. Any coicer, U.S. Patent and TO THIS ADDRES:	the pub minute ommen Trader S. SEN	lic which is to file (and s to complete, includin ts on the amount of tin nark Office, U.S. Depa D TO: Commissioner f	by the USPTO to process) g gathering, preparing, and ne you require to complete rtment of Commerce, P.O. for Patents, P.O. Box 1450,

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Biomeasure Incorporated			ART UNIT	PAPER NUMBER	
27 Maple Street Milford, MA 01757-3650			1654		
Millora, MA 0173	7-3030		DATE MAILED: 05/15/2009		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 413 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 413 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)
	10/522,398	DONG ET AL.
Notice of Allowability	Examiner	Art Unit
	ANISH GUPTA	1654
The MAILING DATE of this communication apperature All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313	ears on the cover sheet with the (OR REMAINS) CLOSED in this or other appropriate communica IGHTS. This application is subje	e correspondence address application. If not included tion will be mailed in due course. THIS
 This communication is responsive to <u>2-5-09</u>. 	and WELF 1300.	
2. The allowed claim(s) is/are <u>1-13, 39-41</u> .		
 3. ☐ Acknowledgment is made of a claim for foreign priority ur a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 		
2. Certified copies of the priority documents have		
3. ☐ Copies of the certified copies of the priority do		
International Bureau (PCT Rule 17.2(a)).		
* Certified copies not received:		
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	IENT of this application.	
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give		
5. CORRECTED DRAWINGS (as "replacement sheets") mus	st be submitted.	
(a) ☐ including changes required by the Notice of Draftspers	on's Patent Drawing Review(P	ΓΟ-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date		
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date	s Amendment / Comment or in th	e Office action of
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t		
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT		
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of Informa	al Patent Application
2. Notice of Draftperson's Patent Drawing Review (PTO-948)	6. ☐ Interview Summ	ary (PTO-413),
3. Information Disclosure Statements (PTO/SB/08),	Paper No./Mail 7. ⊠ Examiner's Ame	Date ndment/Comment
Paper No./Mail Date 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. ☐ Examiner's State 9. ☐ Other	ement of Reasons for Allowance
/Anish Gunta/	<u> </u>	
/Anish Gupta/ Primary Examiner, Art Unit 1654		

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tony Uhm on May 8, 2009.

The application has been amended as follows:

Claims 14-38 have been canceled.

Claim 4 has been amended as follows:

In claim 4, line 50, the following has been deleted:

--(Thr⁶)hGhrelin(1-28)-NH₂; (SEQ ID NO: 13)--.

In claim 4, line 199, on page 10 of the claim set, the following has been deleted:

--(Thr⁶, A5c¹², Orn¹⁵)hGhrelin(1-28)-NH₂; (SEQ ID NO:52)--.

In claim 4, line 225, on page 11 of the claim set, the following has been deleted:

--(Thr 6 , A5c 12 , Apc 16)hGhrelin(1-28)-NH $_2$; (SEQ ID NO:57)--.

The following claims have been added:

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- 39. A compound selected from (Thr⁶)hGhrelin(1-28)-NH₂ (SEQ ID NO: 13), (Thr⁶, A5c¹², Orn¹⁵)hGhrelin(1-28)-NH₂ (SEQ ID NO:52) or (Thr⁶, A5c¹², Apc¹⁶)hGhrelin(1-28)-NH₂ (SEQ ID NO:57) or a pharmaceutically acceptable salt thereof.
- 40. A pharmaceutical formulation comprising a compound from any one of claims 1-13 and 39 with a pharmaceutically acceptable carrier.
- 41. A method of treating cachexia in an individual in need thereof comprising administering to said individual a compound selected from any one of claims 1-13 and 39 or a pharmaceutically acceptable salt thereof in an amount sufficient to treat cachexia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/ Primary Examiner, Art Unit 1654